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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,368	09/30/1999	JOHN R. HAVENS	244/006	6760
34263	7590	08/25/2004		
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			EXAMINER MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 08/25/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/410,368

Applicant(s)

HAVENS ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-17, 21-24, 28-34, 36-39 and 67-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-17, 21-24, 28-34, 36-39, 67, 69, 71-73, 75, 77-82, 84 & 86-89 is/are rejected.
- 7) ☒ Claim(s) 68, 70, 74, 76, 83 and 85 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date (<u>1 sheet</u>). | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 6/7/04, has been entered.

Applicants' arguments, filed 6/7/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

VAGUENESS AND INDEFININTENESS

Claims 28-34 and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At the last line of claim 28, the phrase "a combination of the two methods" lacks clear antecedent basis as to what two methods are meant. Clarification via clearer claim wording is requested. Claims which depend from claim 28 either directly or indirectly also contain this unclarity due to their dependence.

Claim 39 is vague and indefinite due to depending from claim 35 which has been canceled. Clarification via clearer claim wording is requested as to what claim limitations are actually meant to be in claim 39.

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PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-17, 21-24, 28-34, 38, 67, 69, 71-73, 75, 77-82, 84, and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (P/N 5,632,957); taken in view of Sosnowski et al. (P/N 6,051,380).

Heller et al. discloses a microchip device, as summarized in the abstract, which contains microlocations on which reactions, such as nucleic acid hybridization reactions or antibody/antigen reactions, may be controlled in a microscopic format. The device is disclosed as being utilized for nucleic acid hybridization at the microlocations thereon also in column 4, line 48, through column 5, line 17, via binding entities, such as nucleic acids. A device is depicted in Figure 14 with details described in column 17, line 22, through column 18, line 50. An electrode (item 190) is disclosed which is shown in said Figure 14 to be overlaid with a plug of material as described in column 17, lines

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27-37, which thus captures a permeation layer. The permeation layer (column 17, line 38, through column 18, line 4) is made up of material, such as acrylamide (instant claims 87-89) including an attached DNA capture probe attached as disclosed in column 18, lines 5-10. Each lysine group of a poly-L-lysine polymer is a polymerizable moiety, instantly claimed as moiety "P" in instant claim 1 with a covalent bond (Schiff base reaction product), instantly moiety "X" (instant claim 13 covalent bond as well as an amide, ketone, and carbonyl), to which is attached a DNA capture probe (via an oxidized ribonucleoside which is an activation as required in instant claim 24), instantly moiety "R". The lysine groups of the poly-L-lysine are attached in a polymeric molecule which anticipates the bonding of moiety "P" groups of instant claim 1 to other "P" moieties. The poly-L-lysine is thus part of the permeation layer and thus results in a covalent attachment within the permeation layer matrix as required in instant claims 14 and 21. The DNA capture probes are utilized for capture, via hybridization of derivatized biomolecules as described regarding the "R" moiety in instant claim 1, in the reference in that target or reporter DNA is disclosed in column 19, lines 15-42, as being derivatized for fluorescence detection or other derivatizations such as radioactivity, thus indicating that the DNA capture probe clearly anticipates the "R" moiety limitations of the instant invention. It is noted that the DNA capture probe contains amines in nucleobases which is an amine moiety R group as required in instant claims 3, 15, 22, 69, 75, and 84. The lysines of the poly-L-lysine are amine moieties, "P", as containing amine as well as an amide in their structure as required in instant claims 67, 73, and 82. Instant claims 7-11 are

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anticipated in that the covalent structure of the poly-L-lysine attached to the DNA capture probe results in all the "R" and "P" groups being attached to each other as required in various limitations in instant claims 7-11. Poly-L-lysine as the P moieties are the same as being lysines as required in instant claims 12, 16, and 23. Heller et al., however, lacks description of pH change activation of the above described R moiety via a potential applied to at least one electrode of the microarray but is deemed to suggest and motivate any effects which correspond to such electrode practice on microarrays.

Sosnowski et al. also describes a microarray of agents and electrodes equivalent to the above Heller et al. microarray as noted in the abstract, Figures, and DETAILED DESCRIPTION OF THE INVENTION in columns 14-35. The electronic activation of R moieties is additionally described for such microarrays which is required for the control of hybridization reactions as summarized in column 37-43. The electronic potentials applied to various electrodes control hybridization to specific locations on the array vs. others. This electronic potential control at the electrodes produces a pH change in the overlying solution as discussed in column 70, lines 36-61, in the form of a gradient of pH values. These potentials apply electric fields to the arrays as described in column 72, lines 4-6. This is also described as a programmed pH gradient in column 72, lines 20-23, which activates hybridization zones. The microarrays of the reference contain R moieties as oligonucleotide probes which are utilized for hybridization. It is noted that the activation limitation in instant claim 1 lacks any limitation as to what the activation is directed to and therefore is reasonably

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broadly interpreted. Such interpretation thus includes the activation cited in Sosnowski et al. for hybridization. Instant claim 28 etc. has been added to this rejection as being directed to derivatized biomolecule binding which is reasonably available to a variety of nucleic acids which have been modified by labels etc. but yet bind to other nucleic acids via basic hybridization practice.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the microarrays of Heller et al. with the pH activation for hybridization suggested and motivated in such microarrays as set forth in Sosnowski et al. which correspond to electronic activation of electrodes in such microarrays to result in the practice of the instant invention.

CLAIM OBJECTIONS

Claims 68, 70, 74, 76, 83, and 85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 21, 2004

Ardin H. Marschel 8/21/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER